DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Stryker Spine
Garry T. Hayeck, Ph.D.
Senior Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

November 19, 2014

Re: K142251
Trade/Device Name: AVS® AS PEEK Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: August 13, 2014
Received: August 15, 2014

Dear Dr. Hayeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142251

Device Name
AVS® AS PEEK Spacer

Indications for Use *(Describe)*
The Stryker Spine AVS® AS PEEK Spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AVS® AS PEEK Spacers are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an open, anterior approach.

The AVS® AS PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary: Expanded Indications for Use, Stryker Spine AVS® AS PEEK Spacer	
Submitter	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person	Garry T. Hayeck, Ph.D. Senior Regulatory Affairs Specialist Phone: 201-760-8043 Fax: 201-962-4043 E-mail: garry.hayeck@stryker.com
Date Prepared	October 22, 2014
Trade Name	AVS® AS PEEK Spacer
Common Name	Intervertebral fusion device with bone graft, cervical
Proposed Class	Class II
Additional Classification	
• Codification	21 CFR § 888.3080
• Name	Intervertebral body fusion device
Product Codes	ODP
Predicate Devices	The AVS® AS PEEK Spacer was shown to be substantially equivalent to the devices listed below: Primary Predicate Device: Stryker Spine, AVS® AS PEEK SPACER, K120486 Additional Predicate Device: Medtronic Sofamor Danek, ANATOMIC PEEK CERVICAL FUSION SYSTEM, K130177 The components contained in this application are identical to those cleared in K120486 (SE 08/20/2012) with the exception of the inclusion of allogenic cancellous and/or corticocancellous bone graft as an alternative bone graft material.
Device Description	The Stryker Spine AVS® AS PEEK Spacer is a hollow, ring-shaped PEEK Optima® LT1 cage (per ASTM F2026) with three Tantalum marker pins (per ASTM F560). It is intended for use as an interbody fusion device of the cervical spine and is offered in a variety of lengths, heights, and lordotic angles to adapt to varying patient anatomies. The hollow, ring-shaped implant has serrations on the top and bottom for fixation. The hollow space of the implant is intended to hold bone graft material for fusion purposes.
Indications for Use	The Stryker Spine AVS® AS PEEK Spacers are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The AVS® AS PEEK Spacers are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an

	open, anterior approach. The AVS® AS PEEK Spacers are intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.
Summary of Technological Characteristics	The subject AVS® AS PEEK Spacer and the predicates share similar design features: • Graft windows for packing autogenous or allogenic bone • Serrations on the superior and inferior surfaces • Comparable heights, widths, depths, and lordotic angles The purpose of this 510(k) submission is to seek clearance for use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an alternative to autogenous bone graft. No changes have been made to the actual implants.
Summary of the Performance Data	Published clinical data for the cervical interbody fusion devices similar to the AVS® AS PEEK Spacer was provided in support of this application. The published clinical outcomes demonstrated that the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in anterior cervical interbody fusion procedures to treat patients diagnosed with cervical disc disease as defined above does not adversely affect performance of the system and does not represent a new worst case scenario. No changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.
Conclusion	The design features, materials used, manufacturing, and sterilization methods are identical to the previously cleared AVS® AS PEEK Spacer components with the exception of broadening the indications to include the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an alternative graft material. The data presented in this submission demonstrates that the safety and effectiveness of the AVS® AS PEEK Spacers when used with allogenic bone graft comprised of cancellous and/or corticocancellous bone graft is substantially equivalent to the safety and effectiveness of the predicate systems when used with autograft.